

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/ROCKVILLE
1750 ROCKVILLE PIKE, ROCKVILLE, MARYLAND

JANUARY 7 & 8, 2009

AGENDA

On January 7, the committee will discuss new drug application (NDA) 20-427, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of adjunctive therapy for the treatment of refractory complex partial seizures in adults. On January 8, the committee will discuss NDA 22-006, vigabatrin, Ovation Pharmaceuticals, Inc., for the proposed indication of treatment of infantile spasms.

Day 1: Wednesday, January 7, 2009

8:00 a.m. Call to Order and Opening Remarks

Larry B. Goldstein, M.D.

Acting Chair,
Peripheral and Central Nervous System Drugs
Advisory Committee

Introduction of Committee

Conflict of Interest Statement

Diem-Kieu H. Ngo, Pharm.D., BCPS

Designated Federal Official

8:15 AM FDA Introductory Remarks

Russell Katz, M.D.

Director, Division of Neurology Products,
Office of Drug Evaluation I, OND, CDER, FDA

8:30 AM **INDUSTRY PRESENTATION**

10:00 AM Clarifying Questions

10:15 AM **BREAK**

10:30 AM **FDA PRESENTATION**

10:30 AM Ophthalmic Findings in Adults

Ronald Farkas, M.D, Ph.D.

Clinical Reviewer, Division of Neurology Products,
Office of Drug Evaluation I, OND, CDER, FDA

11:30 AM Vigabatrin - Risk Evaluation & Mitigation
Strategies (REMS)

Joyce Weaver, Pharm.D., BCPS

Senior Drug Risk Management Analyst
FDA/CDER/Office of Surveillance &
Epidemiology

11:45 AM Clarifying Questions

12:00 PM **LUNCH**

1:00 PM.	Open Public Hearing
2:00 PM	Questions/Clarifications
3:30 PM	BREAK
3:45 PM	PANEL DISCUSSION/QUESTIONS
5:00 PM	ADJOURNMENT

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AGENDA **-CONTINUED-**

Day 2: Thursday, January 8, 2009

8:00 AM	Call to Order	Larry B. Goldstein, M.D. Acting Chair, Peripheral and Central Nervous System Drugs Advisory Committee
	Conflict of Interest Statement	Diem-Kieu H. Ngo, Pharm.D., BCPS Designated Federal Official
8:15 AM	FDA Introductory Remarks	Russell Katz, M.D. Director, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
8:30 AM	INDUSTRY PRESENTATION	
10:00 AM	Clarifying Questions	
10:15 AM	BREAK	
10:30 AM	FDA PRESENTATION	
10:30 AM	FDA Perspective on Effectiveness	Julia Luan, Ph.D. Statistics Reviewer, Division of Biometrics CDER, FDA
11:00 AM	Ophthalmic Findings in Pediatrics	Ronald Farkas, M.D., Ph.D. Clinical Reviewer, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
11:30 AM	Clinical Studies in Infantile Spasms	Philip Sheridan, M.D. Clinical Reviewer, Division of Neurology Products, Office of Drug Evaluation I, OND, CDER, FDA
12:00 PM	Nonclinical Central Nervous System Pathological Findings	Larry Schmued, Ph.D Division of Neurotoxicology, National Center for Toxicological Research, FDA
12:30 PM.	Clarifying Questions	

12:45 PM **LUNCH**

1:30 PM Open Public Hearing

2:30 PM Questions/Clarifications

3:00 PM **BREAK**

3:15 PM Panel Discussion/Questions

5:00 PM **ADJOURNMENT**

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